FDA Center for Tobacco Products Update
(March 23 – June 22, 2012)

This Progress Report provides an update on the efforts by the FDA Center for Tobacco Products (CTP) in implementing the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). This summary does not reference all actions taken by CTP.

June 2012

CTP Three-Year Anniversary

This summer marks the third anniversary of enactment of the Family Smoking Prevention and Tobacco Control Act. Described as the most far reaching public health intervention in a generation, the Tobacco Control Act mandated the Food and Drug Administration (FDA) to regulate the manufacturing, marketing, and distribution of tobacco products. The upshot is that a vitally important new front has been opened in our nation's ongoing battle against the disease and death caused by tobacco products which, today, claim more than 443,000 U.S. lives annually.

"With the stroke of a pen and strong bipartisan support from Congress, FDA was charged with protecting public health from tobacco use," said FDA Commissioner Margaret Hamburg, M.D. in an op-ed published in Reuters.

"Over the course of the last three years FDA has moved science-based, tobacco-related regulation forward and started a rigorous tobacco research program to enhance the science already available," she said. "The FDA Center for Tobacco Products has focused its efforts on three strategic priorities: preventing initiation, particularly among youth; decreasing the harms of tobacco product use; and, encouraging cessation.

"Working with other federal agencies, including the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), we can make tobacco-related death and disease part of America's past and not America's future."

Richard Turman Named New CTP Deputy Director

In June 2012, FDA Commissioner Margaret Hamburg named Richard J. Turman as CTP's Deputy Director. Prior to joining CTP, Turman served as principal deputy assistant secretary for financial resources at the U.S. Department of Health and Human Services (HHS), where he helped to oversee a 200-person team responsible for developing and managing the department's $900 billion budget and its contract, grant, program integrity, finance, and audit functions. "Richard brings valuable experience, wisdom and proven leadership to CTP and FDA," said CTP Director Lawrence Deyton, M.S.P.H, M.D.

As CTP deputy director, Turman's priorities will include expanding effective communications across FDA and CTP, within HHS, and among stakeholders on matters related to tobacco product regulation and CTP's regulatory authorities.

"In only three years, CTP has earned a reputation as a uniquely effective force for public health," Turman said. "I'm proud that I'll now have the opportunity to help strengthen CTP for years to come."

Turman received his Master's degree in Public Policy from the University of California, Berkeley, and a Bachelor's degree in History and Economics from the University of California, Santa Cruz.

CTP's State Enforcement Program

Since its creation in 2009, CTP has established a vigorous State Enforcement Program under which FDA awards contracts to states and territories to assist with inspections of tobacco retail establishments. Through this initiative, FDA determines whether tobacco retailers are complying with FDA's regulations on youth access, tobacco product advertising, and other provisions of the law that apply to retailers. The first state contracts were awarded in the summer of 2010. As of the end of June 2012, FDA has contracts with 37 states and the District of Columbia and has conducted more than 82,000 inspections of tobacco retailers.

Although most retailers are actively trying to keep tobacco away from kids, there are some who continue to violate the law. More than 3,300 warning letters have been issued to retailers for initial violations, and more than 200 Civil Money Penalty Complaints have been filed against retailers for violating the law. The date, location, and results of all inspections are posted on the CTP website.

- Tobacco Retailer Warning Letters
- Compliance Check Inspections of Tobacco Product Retailers

Youth and Tobacco Town Hall

More than 80 percent of adult U.S. smokers begin smoking as teens. More than 3,800 young people under age 18 smoke their first cigarette each day, and more than 1,000 become daily cigarette smokers. Reversing this trend requires aggressive action on two fronts: reducing the attractiveness of tobacco products to children and ending their access to them. That's exactly what the FDA and its partners are doing.

On June 14, FDA, CDC, and HHS, along with local public health authorities, conducted a Youth and Tobacco Town Hall in Seattle, Washington. CTP Director Dr. Lawrence Deyton, Surgeon General Dr. Regina Benjamin, and CDC Office of Smoking and Health Director Dr. Timothy McAfee joined public health professionals, policymakers, educators, and young people from throughout the Pacific Northwest in the day-long meeting. Participants discussed FDA tobacco product regulation, strategies, and best

practices in tobacco use prevention, by enhancing current efforts and devising new approaches to ensure that youth never start using tobacco.

- Youth and Tobacco Town Hall Meeting and Webcast

Compliance Webinars

CTP hosts regular one-hour webinars to help stakeholders, especially small businesses, comply with FDA tobacco regulations. These webinars are designed to provide retailers and industry with FDA compliance training information. Recent webinar topics have included regulations regarding the limitations on distributing free samples of smokeless tobacco at "qualified adult-only facilities," the import process for small businesses, compliance information on the CTP website, what to expect during an inspection, and substantial equivalence reports. All webinars in this series are archived on the CTP website.

- FDA Tobacco Compliance Webinars – Email Updates
- FDA Tobacco Compliance Webinars – Education and Information for Retailers and Small Businesses

FDA Basics Webinar

CTP also hosted a webinar on June 20 addressing the wide variety of digital tools it uses to engage and inform about tobacco laws. From Twitter to texting, digital technology offers countless opportunities to motivate, inspire action, and present information in new and innovative ways. Participants learned about connecting with social media as well as several tools that can be used to share information.

- FDA Basics Webinar

May 2012

Guidance for Industry

Tobacco manufacturers, importers, researchers, and/or investigators may seek meetings with CTP staff to discuss a range of issues. Topics have included plans to conduct research and/or develop new tobacco products for marketing, informing tobacco product research intended to expand the knowledge needed for FDA regulation of tobacco products, and providing the data needed for premarket review requirements. FDA issued guidance to assist these stakeholders in these processes. Written or electronic comments can be submitted at any time.

- Meetings with Industry and Investigators on the Research and Development of Tobacco Products

FDA Tobacco Regulatory Science Fellowship

CTP launched the FDA Tobacco Regulatory Science Fellowship with the Institute of Medicine. This 12-month, multidisciplinary residential program offers mid-career professionals new expertise to further define and develop the field of regulatory science as it relates to the regulation of tobacco products. Fellows have the opportunity to actively participate in the development of science-based public health strategies, serve as the lead for defined projects, meet with policy leaders, and develop new competencies. Their knowledge, skills, and experiences related to tobacco products and their use can be a valuable asset in reducing the disease and death caused by smoking and other forms of tobacco use.

- FDA Tobacco Regulatory Science Fellowship

April 2012

Two New Research Funding Opportunities

CTP issued two new research funding opportunities on little cigars and clinical pharmacology of tobacco products.

Little Cigars: The purpose of this funding opportunity is to assess if flavored little cigars, because of their appearance or type of tobacco used in the filler, are more likely to be depicted as and consumed by tobacco users as a cigarette. FDA is interested in these data for understanding the risks of little cigars to children and adolescents, how the risks of using these products are perceived by smokers and non-smokers, and how use of these products affects health.

- RFP: Experimental Study on the Subjective, Physiological and Puff Topography Measures of Little Cigars

Clinical Pharmacology of Tobacco Products: The purpose of this funding opportunity is to provide scientific support necessary to evaluate the delivery of nicotine, its metabolites, as well as specific toxic compounds of tobacco products.

- RFP: Research and Analysis of Clinical Pharmacology of Tobacco Products

March 2012

Harmful and Potentially Harmful Constituents (HPHC) List and Draft Guidance

Harmful and potentially harmful constituents (HPHCs) are chemicals or chemical compounds in a tobacco product or tobacco smoke that cause, or could cause, harm to smokers or non-smokers. The Tobacco Control Act requires tobacco product manufacturers and importers to report quantities of HPHCs found in tobacco products or tobacco smoke by brand and sub-brand.

FDA established a list of 93 HPHCs that tobacco companies will be required to report for every regulated tobacco product sold in the U.S. All HPHCs included on the list are linked to serious health problems including cancer, lung disease, heart disease, and addiction to tobacco products.

Recognizing that industry may be unable to meet the deadline due to current testing capacity, FDA released draft guidance on March 30, 2012. The draft guidance identifies 20 HPHCs that are representative of the full list and for which testing methods are widely available; FDA intends to focus reporting enforcement on these 20 HPHCs during 2012. Comments were requested by June 4, 2012. The statutory deadline for testing and reporting quantities of all HPHCs is June 22, 2012. However, CTP does not intend to enforce the statutory deadline as long as reports are received by September 22, 2012 for large manufacturers and December 22, 2012 for small manufacturers.

- Harmful and Potentially Harmful Constituents (HPHCs)
- Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List
- Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry

Modified Risk Tobacco Products (MRTP) Draft Guidance

Modified risk tobacco products are tobacco products that are sold, distributed, or marketed with a claim that they reduce harm or the risk of tobacco-related disease. The Tobacco Control Act establishes rigorous scientific criteria an applicant's tobacco product must meet before FDA will allow the applicant to sell that product with a claim to reduce harm.

On March 30, 2012, FDA released a draft guidance that provides details for those who seek to market a tobacco product as modified or lower risk, including how to organize and submit an MRTP application, what scientific studies and analyses should be submitted, and what information should be collected through post-market surveillance and studies. The deadline for the submission of requests to CTP was June 4, 2012.

- Modified Risk Tobacco Products (MRTPs)
- Modified Risk Tobacco Product Applications: Draft Guidance for Industry

Small Entity Compliance Guide–Final Guidance

On March 28, 2012, FDA released a final guidance for industry entitled ``Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products-Small Entity Compliance Guide'' for a final rule published in the Federal Register on February 2, 2012. This small entity compliance guide explains in plain language the requirements of the regulation and helps small businesses

understand and comply with the regulation. Written or electronic comments can be submitted at any time.

- Small Entity Compliance Guide; Further Amendments to General Regulations of the FDA to Incorporate Tobacco Products

Searchable Tobacco Control Act

CTP released the Searchable Tobacco Control Act and other new tools to make the Tobacco Control Act easier to access, understand, search, and use. CTP also hosted a webinar with a live demonstration.

- Searchable Tobacco Control Act
- New Tools